

FEB 15 2001



K002596

GEBAUER COMPANY

Pharmaceutical Preparations

510(k) SUMMARY

Establishment Name: Gebauer Company
(Manufacturer)

Address: 9410 St. Catherine Ave.
Cleveland, OH 44104

Phone Number: (216) 271-5252

Fax Number: (216) 271-0910

Contact Person: Denise E. Spellman
(Official Correspondent)

Date Summary Prepared: 8/18/00

Device Name: Gebauer's Fluro-Ethyl

Classification Name: Vapocollant

Predicate Products: Fluro-Ethyl
Gebauer's Ethyl Chloride, Fine Pinpoint & Medium
Jetstream Sprays
Frigiderm

Device Description:

Gebauer's Fluro-Ethyl is a prescription device consisting of a mixture of two organic liquefied gases and a precise delivery system. The product is self-aerosolized.

Intended Use of Device:

Gebauer's Fluro-Ethyl is a topical anesthetic refrigerant intended to control pain associated with minor surgical procedures, dermabrasion and injections. It is also intended to provide temporary relief from the pain associated with minor sports injuries.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the new device and the predicate devices aerosolize single or a mixture of two organic liquefied gases. The cooling action experienced by the patient is caused by the evaporation of the liquefied gas or liquefied gas mixture from the patient's skin. One of the predicate devices dispenses a liquefied gas mixture identical to that dispensed by the new device by means of a delivery mechanism (a toggle valve on an aerosol can) that is nearly identical to that utilized by the new device. The other predicates aerosolize one or the other (but not both) of the liquefied gas components in the Fluro-Ethyl mixture.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 15 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Suzanne Wojcik
Director, Regulatory Affairs
Gebauer Company
9410 St. Catherine Avenue
Cleveland, OH 44104

Re: K002596
Trade Name: Fluro-Ethyl
Regulatory Class: unclassified
Product Code: MLY
Dated: November 21, 2000
Received: November 24, 2000

Dear Ms. Wojcik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Mark N. Melherson
Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Gebauer's Fluro-Ethyl

Indications For Use:

Gebauer's Fluro-Ethyl: Gebauer's Fluro-Ethyl is a topical anesthetic intended to control the pain associated with minor surgical procedures, dermabrasion and injections. It is also effective in providing temporary relief from the pain associated with minor sports injuries.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

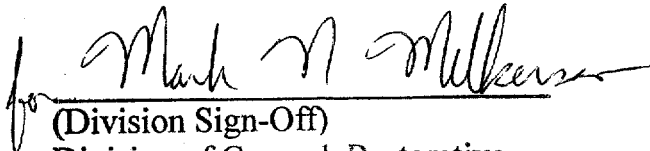
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number _____

K002596